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Applicant	:	Fogel, Barry S.
App. No	:	09/893,244
Filed	:	June 27, 2001
For	:	METHODS OF TREATING TARDIVE DYSKINESIA AND OTHER MOVEMENT DISORDERS
Examiner	:	Williams, Leonard M.
Art Unit	:	1617

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF BARRY S. FOGEL, M.D., UNDER 37 C.F.R. §1.132

I, Barry S. Fogel, M.D., declare and state:

1. I am the sole inventor of the above-referenced application.

2. I received my M.D. degree from the University of California, San Francisco in 1976. From 1976-1977, I was an Intern at Peter Bent Brigham Hospital, Harvard Medical School, Boston, Massachusetts. From 1977-1979, I was a Resident in Neurology, Harvard-Longwood Neurological Training Program. From 1979-1981, I was a Resident in Psychiatry, Stanford University Medical Center, Palo Alto, California. From 1981-1996, I was a faculty member at Brown University Medical School, Providence, Rhode Island (Full Professor 1992-1996). I am currently a Clinical Professor of Psychiatry at Harvard Medical School, with clinical privileges in Neurology and Psychiatry at the Brigham and Women's Hospital in Boston. I am Board Certified in Neurology and Psychiatry with Added Qualifications in Geriatric Psychiatry. I am the Co-founder and a Distinguished Fellow of the American Neuropsychiatric Association. I am the

editor of 10 textbooks and monographs, and author of over 125 articles and book chapters in neurology, psychiatry, geriatrics and long-term care, including *Neuropsychiatry: A Comprehensive Textbook* with Randolph Schiffer and Stephen Rao – one of the leading texts in the field. I am an internationally-recognized specialist in neuropsychiatry.

3. I have personally treated or consulted on the care of over 150 patients with tardive dyskinesia (TD).

4. I have attempted to treat patients suffering from movement disorders, including Tardive Dyskinesia, with magnesium alone. Doses of magnesium have ranged from 205 mg of elemental magnesium once a day to 250 mg four times a day; the specific magnesium preparations have included magnesium oxide, magnesium sulfate, magnesium citrate, and chelated magnesium. I have never seen improvement in TD from magnesium alone, nor has it been reported to me by my patients.

5. In one case, I administered chelated magnesium equivalent to 300 mg of elemental magnesium 3 times per day for 7 days, to a 46 year old man with a simple tic of the neck. No improvement in the frequency or the severity of the tic was observed.

6. Subsequently, acamprosate was administered to the 46 year old man with the simple tic movement disorder discussed in paragraph 5 above. The patient was initially treated with 666 mg acamprosate, three times daily. This resulted in significant reduction in frequency and severity of the tic. About one hour after each dose of the acamprosate the tics would stop; they would recur after another 3-4 hours. When magnesium oxide (a salt rather than a chelate) at a dosage equivalent to 250 mg elemental magnesium, was given three times daily in addition to the acamprosate, the usual tic-free period after each acamprosate dose increased from 3-4 hours to 5-6 hours. Acamprosate with magnesium is also more effective than acamprosate alone in the treatment of Tardive Dyskinesia (TD). The benefit of combining the agents is described in Case Studies 3, 4 and 5 in the specification.

7. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these

statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

7.27.2007
Dated

By: Barry S. Fogel, M.D.

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